



**BILLING CODE: 4163-70-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Toxic Substances and Disease Registry**

**[Docket No. ATSDR-2016-0004]**

**Availability of Draft Toxicological Profile for Ethylene Oxide**

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Agency for Toxic Substances and Disease Registry (ATSDR), within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comments on the Draft Toxicological Profile for Ethylene Oxide.

**DATES:** Written comments must be received on or before

**[INSERT DATE 90 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].**

**ADDRESSES:** You may submit comments, identified by docket number ATSDR-2016-0004, by any of the following methods:

- Federal eRulemaking Portal: [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- Mail: Office of Innovation and Analytics, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., N.E., Mail Stop S102-1, Atlanta, GA, 30329-4027.

Attn: Docket No. ATSDR-2016-0004.

*Instructions:* All submissions must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Henry Abadin, Agency for Toxic Substances and Disease Registry, Office of Innovation and Analytics, 1600 Clifton Rd., N.E., Mail Stop S102-1, Atlanta, GA, 30329-4027, Email: [ATSDRToxProfileFRNs@cdc.gov](mailto:ATSDRToxProfileFRNs@cdc.gov); Phone: 1-800-232-4636.

**SUPPLEMENTARY INFORMATION:**

ATSDR has updated the draft profile based on availability of new health effects information since its initial release. On March 21, 2016 ATSDR announced that it was preparing to develop Draft Toxicological Profiles for public comment release (81 FR 15110), which include Ethylene Oxide. All toxicological profiles issued as "Drafts for Public Comment" represent the result of ATSDR's evidence-based evaluations to provide important toxicological information on priority hazardous substances. ATSDR is seeking public comments and additional information or reports on studies about the health effects of ethylene

oxide for review and potential inclusion in the profile. ATSDR considers key studies for these substances during the profile development process. This document solicits any relevant, additional studies. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion in the profile.

### **Public Participation**

Interested persons or organizations are invited to participate by submitting written views, information, and data.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. ATSDR will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate

examples of a mass-mail campaign. ATSDR will carefully consider all comments submitted in preparation of the final Toxicological Profile and may revise the profile as appropriate.

### **Legislative Background**

The Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 et seq.] amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) [42 U.S.C. 9601 et seq.] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) regarding the hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances [also called the Substance Priority List (SPL)]. This list identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant potential threat to human health. The SPL is available online at [www.atsdr.cdc.gov/spl](http://www.atsdr.cdc.gov/spl).

In addition, CERCLA provides ATSDR with the authority to prepare toxicological profiles for substances not found on the SPL. CERCLA authorizes ATSDR to establish and

maintain an inventory of literature, research, and studies on the health effects of toxic substances (CERCLA Section 104(i)(1)(B); 42 U.S.C. 9604(i)(1)(B)); to respond to requests for health consultations (CERCLA Section 104(i)(4); 42 U.S.C. 9604(i)(4)); and to support the site-specific response actions conducted by the agency.

**Availability**

The Draft Toxicological Profile for Ethylene Oxide will be available online at <http://www.atsdr.cdc.gov/ToxProfiles> and at [www.regulations.gov](http://www.regulations.gov), Docket No. ATSDR-2016-0004.

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